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Assessment of Pharmacoeconomic Evaluations Submitted for Reimbursement in Korea

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ABSTRACT

Objective: To assess the quality of pharmacoeconomic evaluations (PEs) submitted with new drug applications for reimbursement and to investigate the role of PEs for coverage decisions in Korea. **Methods:** Forty-seven PEs that were submitted by pharmaceutical companies for coverage decisions between June 2005 and December 2009 were included in this study. To assess their appropriateness with regard to the PE guidelines, we used the Health Insurance Review and Assessment services (HIRA) checklist consisting of 20 items based on the PE guidelines. We also evaluated the results for coverage decisions, as "recommended," "recommended with restricted use," or "not recommended," based on the incremental cost-effectiveness ratio and the range of uncertainty. **Results:** On average, 14 of the 20 items on the HIRA checklist were fulfilled (70.9%, range 35.0%–100%). The compliance rate for the following items was above 70%: presentation of perspectives and evaluation methods, a sufficient time horizon, and appropriateness of comparators and health outcomes. The compliance rate for the following items was below 70%: omission of objectives for the study, inappropriate target population, unclear selection process for effectiveness and cost, inappropriate cost estimation, insufficient justification of generalizability, and description of study limitations. The range of incremental cost-effectiveness ratios per quality-adjusted life-years of PEs from a societal perspective varied from dominant to 59K USD (n = 13): it consisted of dominant to 28K USD for "recommended" submissions (n = 6), 8K to 20K USD for "recommended with restricted use" submissions (n = 4), and 13K to 59K for "not recommended" ones (n = 3). **Conclusions:** Our study showed that most PEs in this study have reached an adequate level for coverage decisions. Overall barriers associated with a lack of relevant evidence could account for the low compliance rate with specific items in the PE guidelines. PEs with good quality submitted for coverage decisions have played an important role for selecting cost-effective drugs.

Keywords: drug reimbursement, Korea, pharmacoeconomic evaluations, quality assessment.

Introduction

Recently, expenditures on pharmaceuticals are the fastest growing sector within health care. In an attempt to control expenditures and to assess the value of new drugs, economic evaluations are increasingly used by several bodies such as government agencies and managed care groups that determine whether new pharmaceutical treatments should be listed in public formularies [1–6].

Although total spending on health as a share of the gross domestic product (GDP) in Korea is low (6.4% of the GDP in 2006), real health expenditures per capita have increased rapidly over the past decade. The rise in pharmaceutical spending has been one of the factors behind the increase in total health-care spending in Korea [7]. In 2006, spending on pharmaceuticals accounted for 25.4% of total health-care spending, one of the highest proportions in the Organization for Economic Co-Operation and Development area and well above its average of 17.3% [8]. In addition, compared with other countries such as Switzerland, Canada, and Sweden, which are in a positive list system, our previous pharmaceutical benefit schedule in the negative list system consisted of approximately 20,000 drugs, which was huge [9–11]. Under the negative list system, almost all the drugs that were approved by the Korean Food and Drug Administration were automatically listed for reimbursement, and the cost-effectiveness of new drugs was rarely taken into account in coverage decisions. Therefore, it was hard to manage the National Health Insurance reimbursement list efficiently, and nobody knew the monetary value of the listed drugs.

With growing attention to pharmaceutical spending, the Korean government implemented the Health Care System Reform Act effective December 29, 2006. The goal was to convert the pharmaceutical benefit schedule to a positive list system that selects drugs that are both therapeutically effective and cost-effective. This was done in accordance with a rationalization plan for the sustainability of the National Health Insurance. To ensure credibility and objectivity in pharmaceutical reimbursement decision making, the government delegated authority to the HIRA, an independent and specialized agency for reviewing and evaluating health-care technologies. HIRA is responsible for the assessment

Conflicts of interest: All authors have no conflicts of interest with regard to the content of this article.

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Table 1 – The HIRA checklist for quality assessment of pharmacoeconomic evaluations submitted for coverage decisions.

Topic	Questions*
Objectives	Is the object of the study presented in a clear and specific manner?
Perspective	Are the perspective of the analysis and reasons for its selection stated?
Type of evaluation	Is the evaluating method presented and appropriate?
Target population	Is there consistency between evaluated and reimbursed patients?
Time horizon	Does the analytic horizon allow time for all relevant and important outcomes?
Comparator	Are the reasons for the selection of comparator(s) mentioned?
	Is the choice of comparator(s) appropriate?
Data source	Is the methodology for searching and abstracting data clearly stated?
Clinical benefit estimation	Is the clinical evidence unbiased and obtained from the target patients expected to be reimbursed?
Cost estimation	Is the methodology for estimating quantities and unit costs described in a clear and disaggregate way?
	Is the measurement of relative costs appropriate?
Health outcomes	Are the health outcome measures and scales valid and reliable?
Discounting	Has the discount rate been used for both costs and effects?
Model analysis	Are the choice of economic model, main assumptions, and limitations of the study stated and justified?
Uncertainty evaluation	Is sensitivity analysis performed for uncertainty of all assumptions and variables incurring uncertainty?
	Is uncertainty fully handled to cover the range of assumptions?
Generalizability	Are the included data sources proper to generalize the applicable population?
Results	Has an incremental analysis been made?
Budget impact	Has the financial impact been analyzed?
Others	Do the authors explicitly discuss the direction and magnitude of potential biases?

HIRA, Health Insurance Review and Assessment Services.

* Questions, which consisted of 20 items, were developed for assessing appropriateness according to the pharmacoeconomic evaluation guidelines that were developed in Korea for assisting in preparing pharmacoeconomic evaluations for coverage decisions.

on the appropriateness of reimbursement, and the reimbursement restrictions of all submitted drugs by considering the efficiency of drugs and the severity of the disease. In the process of decision making, internal HIRA staff members carefully review submitted dossiers as well as additional data obtained from a comprehensive search, claims data, and experts' opinion. Finally, HIRA is advised by the Drug Benefit Coverage Assessment Committee, which is composed of 18 multidisciplinary members with expertise in medical practice, clinical pharmacology, health economics, pharmacoepidemiology, and other disciplines. According to the Act, pharmaceutical companies that want their new drugs to be listed on the National Health Insurance reimbursement list can, to justify their value for reimbursement, voluntarily submit dossiers following a prespecified form. Pharmacoeconomic evaluations (PEs) were mandatorily requested for drugs, especially ones superior to the comparator drug in terms of clinical benefits but costing more, to justify the higher cost corresponding to the improved effectiveness of drugs. HIRA published the draft guideline in 2005 and the official guidelines in 2006 for PEs. The guidelines assist companies in preparing documents to justify the cost-effectiveness of drugs that can be listed in the national drug formulary [12,13].

Although several countries, such as Canada and Australia, have implemented their own PE guidelines over the past decade, divergence from the guidelines was frequently reported [14–19]. Items for which they were incompliant with the guidelines in the other countries were uncertainty about clinical effectiveness [1], cost estimation [16], and transparency of the methods [14,15,20]. Before HIRA published the PE guidelines, there have also been similar issues for PEs that were published in Korean journals [2]. This study was conducted to evaluate the current state of the PEs that were submitted for coverage decisions by assessing the quality level of the PEs since the development of the PE guidelines. In addition, we investigated the role of the PEs by evaluating the results for coverage decisions in Korea.

Methods

We assessed PEs that were submitted by pharmaceutical companies for coverage decisions and completed for decision making by HIRA between June 2005, when the first PE was evaluated, and December 2009. We analyzed the completed HIRA checklists and HIRA decision documents for submitted PEs and confidential dossiers that were finalized by the pharmaceutical companies according to HIRA's review process. All data extracted for this study were verified retrospectively by independent internal reviewers.

To assess the quality and identify the general features of the PEs, HIRA used the HIRA quality assessment checklist (Table 1) based on the PE guidelines developed in Korea. The checklist was composed of 15 topics and 20 subordinate items that allowed a choice of three responses: "yes," "no," or "not applicable." The compliance rate of each submission was calculated by dividing the number of "yes" responses by the total number of items on the HIRA checklist. The compliance rate of the individual items was calculated by dividing the number of submissions with "yes" responses by the total number of applicable submissions. We also evaluated the quality of the PEs by using the Quality of Health Economic Studies (QHES) instrument to make comparisons with other sites. The QHES checklist contains 16 items and scores each as 0 (lowest quality) to 100 (highest quality) with weighted point values [21]. Mean compliance rates of both checklists and the QHES score were calculated by giving default points on inapplicable topics.

We assessed the compliance rates of all submissions according to coverage decisions, as "recommended," "recommended

with restricted use," or "not recommended." We also evaluated the results of coverage decisions based on the incremental cost-effectiveness ratio (ICER) and the range of uncertainty. Subgroup analysis was done for the PEs that were submitted after the implementation of the new system, because these analyses were mandatory documents needed to justify the cost-effectiveness of drugs subsequent to the reform of the pharmaceutical benefit schedule. Descriptive analysis and the Kurskal-Wallis test were used to identify any significant differences in compliance rates with regard to the coverage decisions.

Results

General characteristics

Overall, 51 PEs were submitted for coverage decisions. Among them, four submissions were withdrawn by pharmaceutical companies before the decision-making process, and these were excluded. The remaining 47 were included in our study, and their general features are presented in Table 2.

Perspective

The PE guidelines request that PEs should present the perspective of the analysis and reasons for its selection, and suggest carrying it out from a societal perspective for the base-case analysis. Of the 47 submissions, 45 (96%) stated the adopted perspectives: 34 (72%) were evaluated from a societal perspective and the other 11 (23%) were analyzed only from a public payer perspective.

Evaluation methods

Of all submissions, 17 (36%) used cost-minimization analysis, 13 (28%) used cost-effectiveness analysis, and 17(36%) used cost-utility analysis.

Time horizon

The PE guidelines recommend that the time horizon should be enough to identify the major health outcome; however, only 33 submissions (70%) were evaluated with analytic horizon to allow time for all relevant outcomes. Of the 47 submissions, 19 (41%) were analyzed for a short period of time (<1 year), 18 (38%) for 1 to 10 years, and 8 (17%) for a period of more than 10 years.

Clinical data sources

The PE guidelines suggest choosing unbiased evidence, such as randomized controlled trials (RCTs) involving the target patients expected to be reimbursed. Of the 47 submissions, 30 (64%) were evaluated by using RCTs, directly comparing the intervention with appropriate comparators; 15 (32%) included RCTs comparing the intervention with inappropriate comparators; and 2 (4%) did not include any RCT evidence in their analysis.

Economic data sources

The PE guidelines recommend using national utilization and unit cost of resources and presenting them in a disaggregate way. Domestic resources for cost data, however, were used in 28 submissions (60%). This consisted of national statistics (n = 10, 21%), hospital chart review (n = 2, 4%), market research data (n = 4, 9%), and clinical expert opinion (n = 12, 26%). In some cases, however, cost resources from foreign countries were used without mentioning the applicability and transferability to domestic circumstances (n = 9, 19%). Of the 47 submissions, 14 (30%) were hard to evaluate because references were unclear.

Table 2 – General characteristics of the pharmacoeconomic evaluations assessed by HIRA.

Item	n	%
Perspectives evaluated		
Societal	34	72
Payer	11	23
Unclear*	2	4
Type of economic evaluation		
CMA	17	36
CEA	13	28
CUA	17	36
Time horizon		
<6 mo	13	28
6 mo–1 y	6	13
1–10 y	18	38
Over 10 y	8	17
Not specified	2	4
Data source		
Effectiveness		
No RCT evidence	2	4
RCT with appropriate comparator(s)†	30	64
RCT with inappropriate comparator(s)	15	32
Cost‡		
National statistics data	10	21
Hospital chart review	2	4
Market research	4	9
Expert opinion	12	26
Data from other PE studies	2	4
Cost data from foreign countries	7	15
Unclear	14	30
Type of health outcomes		
QALY	17	36
Life year saved	6	13
Intermediate (surrogate) outcomes	24	51
Modeling estimation§		
Decision tree	9	45
Markov analysis	11	55
Evaluation of uncertainty		
Deterministic sensitivity analysis	34	72
Probabilistic sensitivity analysis	3	7
None	10	21

n = Number of relevant submissions.
% = Proportions were calculated by dividing the number of relevant submissions on the individual items by the total number of submissions.
CEA, cost-effectiveness analysis; CMA, cost minimization analysis; CUA, cost-utility analysis; HIRA, Health Insurance Review and Assessment Services; PE, pharmacoeconomic evaluation; QALY, quality-adjusted life-year; RCT, randomized controlled trial.
* Perspectives evaluated were unclear to identify health outcome and cost.
† Including placebo treatment if the submitted drugs have no alternative treatment.
‡ The items were counted more than once.
§ Twenty submissions with modeling were submitted (11 submissions after the introduction of a positive list system). Proportions were calculated by dividing the number of relevant submissions by the total number of applicable submissions assessed with submitted models.

Modeling estimation

The PE guidelines request that the analyses present the reason and justification for using a modeling approach as well as assumptions and limitations of the adapted model when such an

Table 3 – Results of quality assessment for the pharmacoeconomic evaluations according to the HIRA checklist.

Topic	Item	All submissions*		Subgroup†	
		n	%	n	%
Objectives	Explicit and clear	27	57	18	53
Perspective	Explicit and clear	42	89	31	91
Type of evaluation	Explicit and clear	47	100	34	100
	Appropriate methodology	36	77	23	68
Target population	Appropriateness of target population -correspondence with indication	27	57	20	59
Time horizon	Enough to identify major health outcome	33	70	24	71
Comparator	Justification of choice	42	89	29	85
	Appropriateness of comparator(s) -comparisons with more than one main comparator when needed	35	74	25	74
Data source	Justification of selection process -search strategy, database -inclusion and exclusion criteria	31	66	23	68
-Clinical benefit estimation	Appropriateness of data source -unbiased clinical data from target patients	35	74	27	79
-Cost estimation	Explicit methodology to estimate cost -disaggregate analysis	32	68	26	76
	Appropriateness of data source, cost item and estimation -reliable and domestic source -inclusive items and rational methods	25	53	22	65
Health outcomes	Appropriateness of health outcomes -final health outcome used -strong relationship between surrogate and final health outcomes if the surrogate outcome was used	42	89	30	88
Discounting	Apply when needed	35	74	32	94
Model analysis‡	Transparency and appropriateness of the analysis -explicit and feasible assumption	7	35	5	45
Uncertainty evaluation	Performance of sensitivity analysis	37	79	27	79
	Enough range to cover uncertainties	29	62	19	56
Generalizability	Justification of generalizability of the results to the target population	22	47	19	56
Results	Presentation of incremental cost-effectiveness ratio	42	89	29	85
Budget impact	Suggestion of budget impact for reimbursement -appropriate assumption and data	40	85	31	91
Others	Explicit justification of the study limitations	13	28	11	32
Total§		47	71	34	73

n = Number of relevant submissions.

% = Proportions were calculated by dividing the number of relevant submissions on the individual items by the total number of submissions.

* All submissions (n = 47) that were assessed between June 2005 and December 2009 were included in this study.

† Submissions in subgroup (n = 34) were assessed between 2007 and 2009 since the introduction of the positive list system.

‡ Twenty submissions with modeling were submitted (11 submissions after introduction of the positive list system). Proportions were calculated by dividing the number of relevant submissions on the item by the total number of applicable submissions assessed by submitted models.

§ "Total" accounts for the average compliance rate of all submissions or subgroup. The compliance rate was calculated by dividing the number of "yes" responses by the total number of whole items composed of the HIRA checklist.

approach was used for estimating the final outcomes, synthesizing the results of several trials, or for other objectives. Modeling approaches were used in 20 submissions (43%), which consisted of Markov models (n = 11, 55%) and decision models (n = 9, 45%).

Uncertainty

Conducting sensitivity analysis with a sufficient range to cover uncertainty is recommended in the PE guidelines. Sensitivity analysis was done for 37 of the 47 submissions (79%). Most (n = 34, 72%) were conducted in a deterministic way; some were done in a probabilistic way (n = 3, 6%).

Quality assessment of submissions

On average, 14 of the 20 items on the HIRA checklist developed according to the PE guidelines were fulfilled (70.9%; range 35.0%–100%). In addition, the mean quality scores and the compliance rate of the QHES checklist were 60.2 (range 30–97) and 62.6% (range 31%–94%), respectively. The mean compliance rate for all submissions and for submissions after the introduction of the positive list system (70.9% and 73.1%, respectively) was similar (Table 3).

Among 20 items on the HIRA checklist, 12 showing compliance rates above 70% included the following: presentation of perspectives and evaluation methods, a sufficient time horizon,

appropriateness of comparator and health outcomes, discounting when needed, sufficient consideration of uncertainty, presentation of ICERs, and suggestion of budget impact for reimbursement.

In contrast, other items with a compliance rate of less than 70% included presentation of study objectives, appropriateness of the target population, transparent processes to select clinical benefit and cost data and a reasonable estimation of them, modeling methods with feasible assumptions, consideration of generalizability, performance of sensitivity analysis with enough range to cover uncertainty, and an explicit description of study limitations. Among them, the target population in only 27 (57%) submissions was identical with the reimbursed population. In addition, 25 (53%) conducted cost estimations as the PE guidelines recommend by using national resource utilization and presenting them in a disaggregate way. Furthermore, the PE guidelines request that the estimating process and the modeling approach should be reported transparently. Only 7 of the 20 submissions (35%), however, in which a modeling approach was used presented analytic methods enough to reproduce the analysis and performed it with appropriate assumptions. In terms of generalizability, 22 (47%) justified the generalizability between the results for the group analyzed in the study and the national target population.

The role of PEs in decision making

The mean compliance rate of PEs with the PE guidelines were not significantly different among coverage decisions ("recommended," "recommended with restricted use," or "not recommended"); they were 69.8% (range 35.0%–95%, n = 23), 74.3% (range 40.0%–95.0%, n = 14), and 68.5% (range 40.0%– 100%, n = 10), respectively.

The cost per QALY in the cost-utility analyses (n = 17) fell in the range from dominant to 59K USD analyzed from a societal perspective (n = 13) and 1.4K to 14.4K USD from a payer perspective (n = 4). The ICERs of the base case along with uncertainty around their estimations analyzed from the societal perspective (n = 13) are shown in Figure 1. These were done according to the Anatomical Therapeutic Chemical classification, which was generated by using the step1 (one-digit) code of the Anatomical Therapeutic Chemical classification system released by the World Health Organization . Based on the ICERs of the base case, they varied from dominant to 28K USD per QALY for "recommended" submissions (n = 6), from 8K to 20K USD per QALY for ones "recommended with restricted use" (n = 4), and from 13K to 59K USD per QALY for ones that were "not recommended" (n = 3).

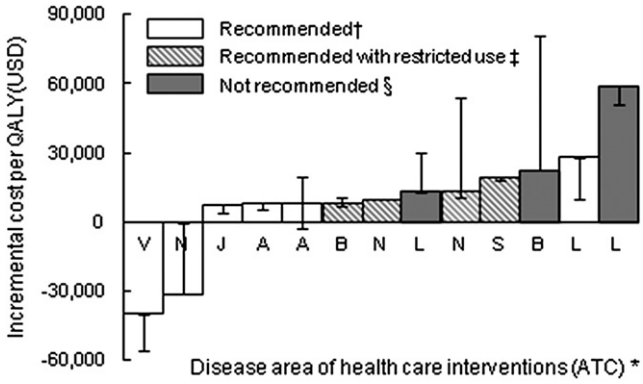

Fig. 1 – Ranked ICER per QALY including uncertainties for the submissions that used cost-utility analysis from societal perspectives. Bar (I) = Range of uncertainties by sensitivity analysis. *Disease areas of health-care interventions were presented by the Anatomical Therapeutic Chemical (ATC) code. †The medicines that the Health Insurance Review and Assessment Services (HIRA) recommended to be listed according to the approved label by the Korean Food and Drug Administration (KFDA). ‡The medicines that HIRA recommended to be listed within the limited range for the submitted drug, which was different from those in a similar therapeutic class. §The medicines that HIRA decided not to recommend. A (alimentary tract and metabolism), B (blood and blood-forming organs), C (cardiovascular system), G (genitourinary system and sex hormones), H (systemic hormonal preparations, excluding sex hormones and insulins), J (anti-infectives for systemic use), L (antineoplastic and immunomodulating agents), N (nervous system), R (respiratory system), S (sensory organs), V (various). ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; USD, US dollar. (The Korean won [KW] was converted at a rate of 1165 KW per USD, which was the monthly average exchange rate in December 2009.)

Discussion

It has been 3 years since the reform of the pharmaceutical benefit schedule, which resulted in PEs becoming an official requirement in coverage decisions on newly introduced drugs. There were some concerns, such as the lack of expertise, experience, and local data, to conduct PEs in the early stage of the new system [22,23]. However, the 47 PEs that had been submitted for coverage decisions addressed the overall quality level as being approximately at 70% according to the HIRA checklist assessment.

There is no universal and standard instrument for the quality assessment of PEs submitted for coverage decisions. Most of the quality assessment studies were previously conducted by using checklists according to the guidelines developed by individual countries. For the rational coverage decisions, HIRA also assessed the quality level of the PEs submitted for reimbursement in accordance with the PE guidelines in Korea. Besides using the HIRA checklist, we tried to make direct comparisons between our study and other studies by using the QHES checklist.

Comparable material was evaluated by using the QHES checklist, which was about quality assessment of PEs submitted to the Pharmaceutical Benefit Board, the Swedish decision-making committee for medicines that is similar to the Drug Benefit Coverage Assessment Committee in Korea. It showed a broadly similar quality level to our study (n = 47, 63%, and n = 20, 70%; Drug Benefit Coverage Assessment Committee and Pharmaceutical Benefit Board, respectively) in terms of the mean compliance rate with the QHES checklist [24]. In addition, there were several studies that identified the extent of compliance with their individual PE guidelines or with the QHES checklist. Although direct comparisons between the previous studies and our study were limited, because each of the results was generated for a specific disease area, such as gastroesophageal reflux disease [21,25], or did not reflect the appraisals for reimbursement [16], their quality level was similar to that of our study.

Several items with the lowest compliance rate, such as inappropriateness of target population, cost estimation, and modeling methods with feasible assumptions, might result from the lack of relevant evidence and resources, which has caused continuous controversy about the uncertainty of the estimation [1,17]. Especially for cost estimation, this tendency looks similar even in Canada, which has been conducting PEs for over a decade, and where there have been continuous problems regarding the lack of national statistics in terms of the availability of cost and resource data [16]. In addition, the uncertainty of the PEs grows because of

the use of impractical assumptions in modeling analysis because of the lack of relevant evidence to apply. And all these could affect generalizability, which showed low compliance as well. As for generalizability, efficacy data cited from clinical trials for modeling approaches were limited to reflect real-world effectiveness. Also, data from clinical trials conducted in foreign countries were difficult to apply directly to the local target population without considering the differences in demographic characteristics of the population, the treatment pattern for the disease, and differences in the use of comparators. To solve this problem with lack of clinical evidence and efforts to secure clinical evidence, the government started conducting national clinical trials [26] and analyzing the outcomes of health-care technologies [27]. These efforts could be the starting point for solving the uncertainty issues around cost-effectiveness for the reimbursement of pharmaceuticals and make a solid base for evidence-based decision making.

The cost-effectiveness ratio has been considered one of the major factors having a decisive effect on recommendations [28]. There are known ranges of cost-effectiveness that were retrospectively drawn [3,29,30]. Most of the decision-making bodies, however, have no fixed ICER threshold, and they also consider the existence of other alternatives and innovations in health technologies [31–34]. HIRA also considers cost-effectiveness as one element among other decision criteria, including clinical benefit, budget impact, reimbursement status in other countries, and other features that may affect public health. Therefore, for assessing cost-effectiveness, HIRA does not have a fixed ICER threshold. Instead, it decided to consider the per capita GDP (26K USD, 2007 [35]) as a reference value and made flexible judgments based on disease severity, societal burden, quality of life, and innovations. In addition, HIRA has been trying to make coverage decisions considering the substantial range of uncertainty around cost-effectiveness, which was similar to the previous decisions of the Common Drug Review and the Pharmaceutical Benefits Advisory Committee that the reimbursement rates were lower when there were considerable clinical or economic uncertainties [1]. For instance, HIRA did not recommend the drug for recurrent stroke treatment presented as "B" in Figure 1 for which the ICER of sensitivity analysis increased by 2 times compared with that around the per capita GDP of the base-case analysis. On the contrary, it recommended listing the drug for metastatic breast cancer therapy (presented as "L" with an open bar graph in Fig. 1), even though the ICER of the drug was higher than the per capita GDP, because the drug satisfied the need of patients with severe disease and showed solid cost-effectiveness with respect to the range of uncertainty.

Generally, submissions with low-quality level were not recommended because of high uncertainty of the results. In this study, however, the overall quality level of PEs of drugs submitted for reimbursement was 70.9% (mean, n = 47), which was similar among coverage decisions. Also, the overall ICER of the base-case analysis tends to increase gradually according to the order of coverage decisions ("recommended," "recommended with restricted use," or "not recommended"). This shows that HIRA made coverage decisions with the PEs that were adequate for decision making. Therefore, individual decisions could be made by considering the result of cost-effectiveness with uncertainty and the specified criteria such as clinical benefit, budget impact, reimbursement status in other countries, and the other features that may affect public health. Further analysis, however, will be required as the number of decision materials grows, because it was difficult to identify the factors that affect the coverage decisions in depth because only 17 submissions presented the ICER per QALY, a relatively small number. In addition, the decision-making process applied to the PE submissions could be different in details, because we improved the process consistently for the stable and feasible implementation of the new system. This limitation, however, may not a crucial flaw of this study, because the framework of the criteria was identical regardless of the applied period.

Conclusions

This study was performed to assess PEs submitted for coverage decision and to present the role of PEs in decision making for the first time in Korea. Most of the submissions for coverage decisions reached a level that was adequate for decision making by HIRA. The overall barrier for conducting PEs was a lack of relevant evidence to use. PEs with good quality submitted for coverage decisions in Korea have played an important role for selecting cost-effective drugs by providing useful information. This study could be helpful for understanding the present state of the PEs submitted for coverage decisions in Korea and could be valuable for suggesting items that need to be improved to have better appraisals.

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